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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,031	05/01/2006	J. Keith Joung	62046(51588)	6686
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EDWARDS ANGELL PALMER & DODGE LLP			EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/532,031

Applicant(s)

JOUNG, J. KEITH

Examiner

SUE LIU

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF 298)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claim Status

Claims 1-61 are currently pending.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-10, drawn to a non-naturally occurring NRSE-based zinc-finger polypeptide.

Group 2, claim(s) 11, drawn to a method of regulating the expression of a gene.

Group 3, claim(s) 12, drawn to a method of altering the structure of a nucleic acid molecule.

Group 4, claim(s) 13, drawn to a method of altering the structure of a chromatin.

Group 5, claim(s) 14, drawn to a method of cleaving a sequence of interest.

Group 6, claim(s) 15, drawn to a method of silencing a gene.

Group 7, claim(s) 16-20, drawn to a method of selecting a non-naturally occurring NRSE-based zinc finger.

Group 8, claim(s) 21-22, drawn to a method of selecting a non-naturally occurring NRSE-based zinc finger using primary libraries.

Group 9, claim(s) 23-27, drawn to a nucleic acid library.

Group 10, claim(s) 28, drawn to a DNA sequence of interest.

Group 11, claim(s) 29, drawn to a DNA sequence with SEQ ID No. 13.

Group 12, claim(s) 30-40, drawn to a non-naturally occurring scaffold-based zinc-finger polypeptide.

Group 13, claim(s) 41, drawn to a method of regulating the expression of gene.

Group 14, claim(s) 42, drawn to a method of altering the structure of a nucleic acid molecule.

Group 15, claim(s) 43, drawn to a method of altering the structure of chromatin.

Group 16, claim(s) 44, drawn to a method of cleaving a sequence of interest.

Group 17, claim(s) 45, drawn to a method of silencing of a gene of interest.

Group 18, claim(s) 46-50, drawn to a method of selecting a non-naturally occurring scaffold-based zinc-finger.

Group 19, claim(s) 51-52, drawn to a method of selecting a non-naturally occurring scaffold-based zinc-finger using primary libraries.

Group 20, claim(s) 53-61, drawn to a nucleic acid library.

2. The inventions listed as Groups 1-20 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The linking features of Group 1-20 are structurally and functionally different from one another. For examples, the linking feature of Group 1 is a non-naturally occurring NRSF-based zinc-finger polypeptide; the linking feature of Group 2 is a gene of interest; the linking feature of Group 3 is a nucleic acid molecule. Therefore, Groups 1-20 are not so linked by the same or a corresponding special technical feature as to form a single inventive concept. In addition, the special technical feature of Group 1 is known in the prior art. For example, Shimojo et al

(Journal of Biological Chemistry, Vol. 276: 13121-13126, 1/5/2001; cited in IDS) teach mutant NRSF zinc finger polypeptide having at least one zinc finger with mutated amino acid residues that have various binding properties with consensus sequences (see entire document; Figures), which reads on the non-naturally occurring NRSF zinc finger polypeptide as recited in the instant claim 1. Thus, the inventions lack unity.

Species Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicants are requested to further elect a **single ultimate species for each** of the following:

- a. A single specific selection of a polypeptide either with OR without a “functional domains” (for Groups 1 and 12).
 - i. If Applicants elect a polypeptide with a functional domain, applicants are further requested to elect a single specific type of functional domain. (e.g. claims 6-10).
- b. A single specific polypeptide expression system for expressing the zinc finger polypeptide. (For Groups 7 and 18; e.g. claims 18-20).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. The claims are deemed to correspond to the species listed above in the following manner:

The claims are deemed to correspond to the species listed above in the following manner: Please see the above species selection for correspondence between the claims and the species selection.

The following claim(s) are generic: 1-61.

The species lack the same technical feature, because they do not share a common core structure and/or function. The different species would also differ in their reactivity and the starting materials from which they are made. For examples, the different species of “functional domains” can be of various protein structures and/or functions, which species do not share the same core structure and do not have the same function. Similarly, the different species of “expression systems” are also structurally and/or functionally different from each other. For different species of method, the method steps for each species would differ. Consequently, the

species have different issues regarding patentability. Thus the unity of invention between each species subgroup is lacking.

Applicant is advised that the reply to this requirement to be complete must include **(i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sue Liu/
Patent Examiner, AU 1639
1/15/09